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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/301,704	04/29/99	SCHEMBRI	54259.800002

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NM12/1023

EXAMINER
SHEINBERG, M

ART UNIT	PAPER NUMBER
1631	20

DATE MAILED: 10/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/301,704

Applicant(s)

SCHEMBRI ET AL.

Examiner

Monika B. Sheinberg

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 16, 17 and 26-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 18-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 April 1999 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner. (See PTO-948)
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 sheets.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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**DETAILED ACTION**

***Drawings Notice***

Applicant is hereby notified that the required timing for the correction of drawings has changed. See the last 6 lines on the sheet which is attached to the back of the PTO-948, entitled "Attachment for PTO-948 (Rev. 03/01 or earlier)". Due to the above notification Applicant is required to submit drawing corrections within the time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

***Sequence Non-Compliance Notice***

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR § 1.821 through 1.825 because Figures 1 and 6 contain sequences. A Sequence Listing and a computer readable format of it must be provided with a statement that the two are identical. Applicant is reminded that CD-ROM sequence listings are now accepted instead of a paper copy of the sequence listing for the specification. The sequences presented in the figures must still be included in the Sequence Listing; and a sequence identifier (SEQ ID NO: X) must be used, either in the drawing or in the Brief Description of the Drawings. Applicant(s) are given the same response time regarding this failure to comply as that set forth to respond to this office action. A complete

Art Unit: 1631

response to this office action includes compliance with this sequence rule compliance. Failure to comply may result in abandonment of this application.

*Election/Restrictions*

Claims 16,17, and 26-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected groups, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 19, filed August 16, 2001.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 and 18-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, 4-6, 10, 18, and 25 are vague and indefinite due to the use of the language “first kind” and “second kind” as for example in line 3 of claim 1. Such terminology is indicative of a sequential order of steps, however the claim 1 recites them as if they must be expressed on the surface of the claimed recombinant cell at the same time. This contradicts what is present within the specification on page 6 (lines 23-26) defining the “second kind” of binding region to derived from the “first kind” of binding region. Thus claim 1 lacks clarity as to the confusing terms used to describe the binding regions. The same occurs in claim 6, where the adhesin is said to express “first and second kind of binding domains”, lines 5-6. As such, claims drawn to the use of the

Art Unit: 1631

first or second binding regions are also rendered vague and indefinite (claims 2-3, 7-9, 11-15, and 19-24).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 12, 13, 15, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sousa et al. (*Proc. Natl. Acad. Sci.*, 1992).

Sousa et al. suggest the use of “flagellar proteins of Gram-negative bacteria as anchor sites for peptides” (p. 1017, 1<sup>st</sup> column, 1st paragraph). The reference further points to the examination of designing these proteins with metal-binding properties with the use of “one or two histidine (His) clusters” (p.1017, 1st column, 2<sup>nd</sup> paragraph) with peptides of various lengths upon *Escherichia coli* cells; adhesion to a Ni compound is suggested on page 1019 (1<sup>st</sup> column,

Art Unit: 1631

2<sup>nd</sup> paragraph) as seen in claim 10, line 3. The enrichment of the cell population containing these Ni compound binding heterologous proteins is suggested by the use of their adhesion to beads described on page 1019 (2<sup>nd</sup> column, 4<sup>th</sup> paragraph). Although, Sousa et al. practices the method upon a LamB protein, the claimed FimH protein is also a cell surface fibril; thus Sousa et al. motivates the recombinant cells of claims 1, 2, 12, 13, 15, and 18.

Claims 1-10, 12, 13, 15, and 18-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sousa et al. (*Proc. Natl. Acad. Sci.*, 1992) as applied to claims listed above, and further in view of in view of Pallesen et al. (*Microbio.*, 1995) and Georgiou et al. (*Nat. Biotech.*, 1997).

Pallesen et al. describes a method of engineering a chimeric FimH adhesin by way of insertion into plasmids; for DNA segment for example that is "162 nucleotides encoding 52 [...] amino acids" (p. 2842, 2<sup>nd</sup> column, 2<sup>nd</sup> paragraph). A heterologous epitope on a FimH component is clearly displayed in Figure 2, page 2840. Georgiou et al. within the abstract, in view of Sousa et al and Pallesen et al., clearly motivates the display of peptide libraries encoding heterologous proteins in bacteria, in particular E. coli, as recited in claims 18-25.

### ***Information Disclosure Statement***

The information disclosure statement filed October 13, 1999, fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the reference (G) Schembri et al (FEMS Microbio. Letters, 1999) is illegible. It has been placed in the application file, but the information referred to therein has not been considered as to the merits.

Art Unit: 1631

*Inquiries*

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monika B. Sheinberg, whose telephone number is (703) 306-0511. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

October 22, 2001

Monika B. Sheinberg  
Art Unit 1631

*MBS*

*Ardin H. Marschel*  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER